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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,329

11/18/2003

Fred H. Burbank

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Doherty IP Law Group LLC  
37 Belvidere Ave  
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,329	<b>Applicant(s)</b> BURBANK ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 65-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-68, 75-79, and 81-84 is/are rejected.
- 7) ☒ Claim(s) 69-74 and 80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to Applicant's amendment received on 25 May 2008. Claims 1-64 have been cancelled and new claims 65-84 have been added.

#### ***Response to Arguments***

1. Applicant's arguments with respect to claims 65-68, 75-79, and 81-84 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 81-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose the driving member engages the medical instrument. Rather, the applicant disclosed the driving member engages a collar that engages and urges the medical instrument to slide over the outer surface of the guide rail. Therefore, this limitation is considered new matter.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65-68 and 81-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasson (5,368,598). Hasson discloses an intravaginal device (see entire document) comprising an elongated guide rail (60) including a threaded section (graduations 134 form a thread-like section), a slidable collar (172 via attachment sleeve 174 over which a medical device is slidable over) mounted on the outer surface of the guide rail (therefore is slidable over the threaded section), a driving member (108) having internal threads (stepped bore 126 forms an internal thread-like surface which may engage any portion of the guide rail, including the threaded section), a tissue grasping assembly (124) including a first elongated element connected to the outer surface of the guide rail via the driving member and a second elongated element pivotally connected with the first elongated element via a pivot pin (for example, see Fig. 5), wherein both elements inherently have a tissue grasping element at the distal end in that they are used to grasp tissue (distal ends grasp the cervix; for example, see Fig. 5), and a medical instrument (cervix sealing member 166) slidably mounted on the outer surface of the guide rail between the collar (174) and the connection of the first element (which is at the location of the driving member), wherein the driving member is capable of rotating and if rotated towards the distal end of the guide rail, the collar will slide towards the distal end due to the pressure applied by the medical instrument, thus allowing the medical instrument to urge towards the distal end of the guide rail. With

further respect to claims 68 and 84, the proximal end of the driving member is accessible at the proximal end of the guide rail in that it may be grasped by a user.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson in view of Martin (3,320,948). Hasson discloses the claimed invention (see paragraph 3 above for similar limitations) except for a distal end of the elongated member being connected with the outer surface of the guide rail. Martin discloses an intravaginal device (see entire document) comprising a guide rail (3) and a tissue grasping assembly (2). Hasson teaches the tissue grasping assembly has a distal end connected with the outer surface of the guide rail (for example, see Figure 1). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the distal end of Hasson's elongated member to the guide rail as taught by Martin. Doing so would provide more stability to the tissue grasping member.

***Allowable Subject Matter***

7. Claims 69-74 and 80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 69-74, the prior art fails to disclose, teach, or suggest that the first elongated element is connected with the outer surface of the guide rail between the collar and the distal end of the guide rail. Regarding claim 80, the prior art fails to disclose, teach, or suggest a connecting plate for interconnecting the distal end of the elongated element with the guide rail, wherein the connecting plate includes a surface adapted to engage the attachment sleeve for halting distal sliding movement of the attachment sleeve toward the distal end of the guide rail. One would not be motivated to modify the Hasson reference as claimed, since such a modification would require portion 108 to be distal portion 166. This configuration would render Hasson's device inoperable in that the tenaculum would be positioned within the cervical canal, thus would be incapable of gripping the outside surface of the cervix, would interfere with sealing the cervical opening, and possibly damage the cervical canal and/or uterine cavity.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
July 30, 2008

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773